

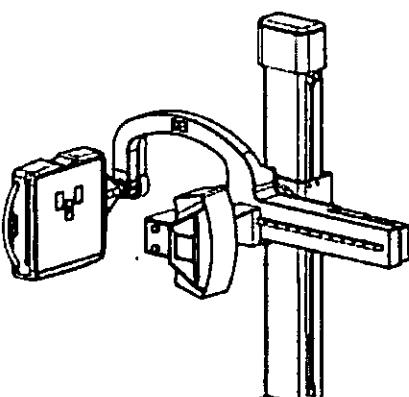
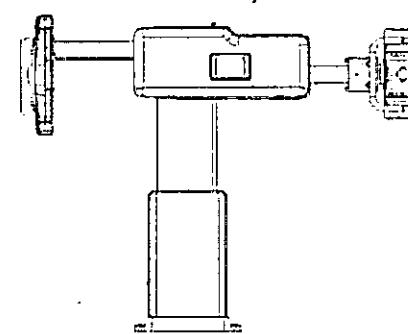
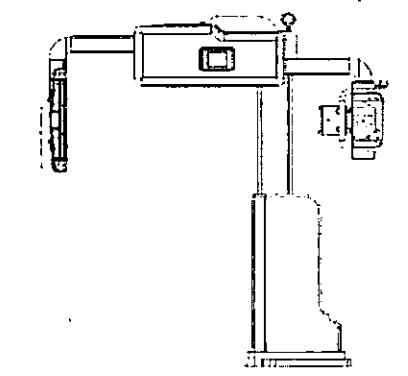
510(k) Summary K132294

1. Submitter:
RADIOLOGY SOLUTIONS LLC
1912 Golfcrest Dr
Commerce Twp, MI 48382
Tel. 866.681.6681
Date Prepared: October 10, 2013
Contact: Scott Milgrom, President
- NOV 12 2013*
2. Identification of the Device: Galaxy and Galaxy+ Plus Digital Diagnostic X-Ray System.
Classification Name: Stationary x-ray system ; Common/Usual Name: Stationary x-ray system
Regulation Numbers: 21 CFR 892.1680, Product Codes: MQB and KPR
3. Predicate Device: The Galaxy systems are substantially equivalent to The Sedecal X-Plus LP Plus Digital Diagnostic X-Ray Systems, K090238.
4. A description of the device: This is a complete stationary diagnostic x-ray system employing a digital x-ray panel coupled with image acquisition software. The acquisition software is installed on a Windows compatible workstation. The high frequency generator is available in four different power ratings. All components are either 510(k) exempt or previously cleared. The only difference between the two models is the configuration of the tube stand. Galaxy has a straight arm and the Galaxy+ Plus is in a U-Arm configuration. Generators are available in 40-50-65-or 80 kW (High Frequency) models.
5. Indications for Use: Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)
6. The Galaxy and Galaxy Plus have essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device Sedecal. See the comparison table below. There are really only a few main differences: The digital panels, x-ray generator, and tube stands are from different manufacturers but with functionally identical capabilities.

Comparison Table

Characteristic	Predicate Device The Sedecal X-Plus LP Plus Digital Diagnostic X-Ray Systems, K090238.	Galaxy and Galaxy+ Plus
Indications	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)
Digital Receptor Panel	CANON panels, multiple models: 50C, 50G, 40C & 40G (Various clearances)	Atlaim ATAL 8 AND ATAL 8C (Cleared in K113812) to be known as "IRIS" AND "IRIS C"

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Characteristic	Predicate Device The Sedecal X-Plus LP Plus Digital Diagnostic X-Ray Systems, K090238.	Galaxy and Galaxy+ Plus
Panel Communication	Tethered Ethernet, one panel	Same
Panel Resolution	Pixel size $160 \times 160 \mu\text{m}$ Image matrix size 2208×2688 pixels Number of pixels Approx. 5.9 million pixels	Pixel size $139 \times 139 \mu\text{m}$ Image matrix size 3072×3072 pixels Number of pixels Approx. 9.4 million pixels
DICOM	Yes	Yes (Same software as cleared in K112527) to be known as "Nexus"
Tube Stand	U-Arm	One model is a straight arm, the other is similar to a U-Arm. See below
Generator	Sedecal 65 kW, optional 80 kW (High frequency)	CPI, 40-50-65-or 80 kW (High Frequency)
Safety	UL Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards	UL/CSA Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards
Photo		 Galaxy  Galaxy+ Plus

7. Description of non-clinical tests. The unit has undergone electrical safety and electromagnetic compatibility testing, as well as software validation and risk analysis. The unit meets IEC safety and EMC standards. The technical characteristics of the new system have been measured and included in the bench testing information performed by a radiology physicist.
8. Description of clinical tests. Clinical images were obtained in accordance with the FDA Guidance Document on Solid State Imaging Devices. They were evaluated by professional radiologist and found to be of good diagnostic quality.
9. Conclusions drawn: The nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 3, above.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

Radiology Solutions LLC
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K132294

Trade/Device Name: Galaxy and Galaxy+ Plus Digital Radiography Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR and MQB
Dated: August 12, 2013
Received: August 15, 2013

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132294

Device Name: Galaxy and Galaxy+ Plus

Indications for Use:

Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. (Not for mammography)

Prescription Use

AND/OR

Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

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